HEALTH AND SENIOR SERVICES

DIVISION OF HEALTH CARE QUALITY AND OVERSIGHT

Hospital Licensing Standards

Proposed Readoption with Amendments: N.J.A.C. 8:43G

Proposed Repeal and New Rules: N.J.A.C. 8:43G-30

Authorized by:	Fred M. Jacobs, M.D., J.D., Acting Commissioner, Department of Health and Senior Services (with approval of the Health Care Administration Board).
Authority:	N.J.S.A. 26:2H-1 et seq.
Calendar Reference:	See Summary below for explanation of exception to calendar requirement.
Proposal Number:	PRN 2005-74

Submit comments by May 6, 2005 to:

John A. Calabria, Director
Certificate of Need and Acute Care Licensure Program
New Jersey Department of Health and Senior Services
P.O. Box 360
Trenton, New Jersey 08625-0360

The agency proposal follows:

Summary

Pursuant to N.J.S.A. 52:14B-5.1c, N.J.A.C. 8:43G, Hospital Licensing Standards, is scheduled to expire on January 27, 2005. The

Department of Health and Senior Services (the Department) has reviewed N.J.A.C. 8:43G and, with the exception of amendments described below, has determined the existing rules to be necessary, proper, reasonable, efficient, understandable, and responsive to the purposes for which they were originally promulgated. In accordance with N.J.S.A. 52:14B-5.1c, the filing of this notice of proposal prior to January 27, 2005 extends the chapter's expiration date to July 26, 2005.

The Department is proposing the readoption with amendments of the hospital licensing standards to update and revise licensure standards for all licensed general and special hospitals. The Department is also proposing technical amendments which would reflect changes in contact information such as address, telephone number and website, as well as changes in organizational designation from "Inspections Program or the Licensing and Certification Program" and "Certificate of Need Licensure Program" to "Certificate of Need and Acute Care Licensure Program" and from "Division of Health Facilities Evaluation and Licensing" to "Division of Health Care Quality and Oversight." In addition, the Department is proposing that N.J.A.C. 8:43G-2.3 be amended to reflect that, pursuant to Reorganization Plan No. 004-1996, the Governor has transferred responsibility for construction plan review and construction code enforcement in health care facilities and, therefore, approval of final

construction of the physical plant of newly constructed or expanded facilities, from the Department of Health and Senior Services to the Department of Community Affairs.

The Department is also proposing to repeal and establish new rules at Subchapter 30, which governs renal dialysis services. The proposed repeal and new rules are the work of a committee, composed both of representatives from the Department and of renal dialysis professionals from New Jersey's health care industry, which was convened to review and revise licensing standards for renal dialysis in both hospitals and ambulatory care facilities. The primary aim of this effort was to update the renal dialysis standards, which have not been substantially revised since 1990, to reflect current renal dialysis practice patterns. However, the proposed repeal and new rules are also an attempt to carry out the State Legislature's stated intent in P.L. 1998, c.43 to rely less on the certificate of need process and more on licensure and inspections of health care facilities to ensure the provision of high quality health care to New Jersey citizens. The proposed amendments, repeal, and new rules reflect the Department's commitment to protect the public health and safety through the rulemaking process, pursuant to N.J.S.A. 26:2H-1 et seq.

N.J.A.C. 8:43G became effective on January 27, 2000. These licensing standards have enabled general hospitals to deliver a high level

quality of care to patients in acute care hospitals. The proposed readoption with amendments, repeal, and new rules would maintain (as well as re-establish in the case of renal dialysis services) minimum requirements for safe operation of an acute care hospital. Individual facility compliance is assessed through the Department's oversight activities, specifically its facility survey and inspection process.

The Hospital Licensing Standards proposed herein for readoption address the full range of acute care hospital licensure requirements, as follows:

Subchapter one establishes general provisions of hospital licensure. N.J.A.C. 8:43G-1.1 sets forth the scope and purpose of the chapter. N.J.A.C. 8:43G-1.2 sets forth definitions of words and terms used throughout the chapter. N.J.A.C. 8:43G-1.3 sets forth the different classifications of acute care hospitals covered by these rules (private, non-profit; private, proprietary; public hospital; general hospital; special hospital; psychiatric hospital). N.J.A.C. 8:43G-1.4 provides contact information for individuals who seek information about licensure or who wish to file a complaint against a licensed facility.

Subchapter two establishes procedures to obtain and maintain licensure. N.J.A.C. 8:43G-2.1 concerns the certificate of need procedures required prior to licensure. N.J.A.C. 8:43G-2.2 sets forth the application

procedure required for licensure. N.J.A.C. 8:43G-2.3 concerns newly constructed facilities. N.J.A.C. 8:43G-2.4 involves surveys and temporary licensure. N.J.A.C. 8:43G-2.5 concerns full licensure. N.J.A.C. 8:43G-2.6 sets forth the process for revocation or suspension of licensure. N.J.A.C. 8:43G-2.7 concerns licensure surrender. N.J.A.C. 8:43G-2.8 establishes waiver of licensure requirements. N.J.A.C. 8:43G-2.9 sets forth the provisions for action against a licensee. N.J.A.C. 8:43G-2.10 indicates the requirements for information that is non-disclosable. N.J.A.C. 8:43G-2.11 concerns hospital satellite facilities and off-site ambulatory care service facilities. N.J.A.C. 8:43G-2.12 addresses mandatory services provided in general and psychiatric hospitals. N.J.A.C. 8:43G-2.13 sets forth requirements hospitals must follow in situations of child abuse and neglect.

Subchapter three is reserved.

N.J.A.C. 8:43G-4 establishes what is commonly known as the hospital patient's bill of rights. The subchapter provides a list of the rights afforded to every New Jersey hospital patient under N.J.S.A. 26:2H-12.8 (Bill of rights for hospital patients), and explains that none of those rights shall be abridged by the hospital or any of its staff. Moreover, the subchapter requires that hospital administrators shall be responsible for

developing and implementing policies to protect patient rights and to respond to questions and grievances pertaining to patient rights.

The Department is proposing that N.J.A.C. 8:43G-4.1 be amended to add a new paragraph "31," which would contain an additional hospital patient right, namely, the right to expect and receive appropriate assessment, management and treatment of pain as an integral component of that person's care. This amendment is necessitated by P.L. 2000, c.65, which amended N.J.S.A. 26:2H-12.8, adding the above-mentioned right to the list of rights enumerated in the hospital patient's bill of rights. In addition, the department is proposing that new paragraph "31" contain a cross-reference to N.J.A.C. 8:43E-6, which sets forth the Department's requirements for health care facilities licensed under N.J.S.A. 26:2H-1, et seq., in the area of assessment, monitoring and management of pain. It is the Department's intent in including this cross-reference within proposed N.J.A.C. 8:43G to its pain management standards published elsewhere in the New Jersey Administrative Code, to assist the regulated community in complying with the appropriate standards. Section 4.2 is reserved.

Subchapter five establishes the requirements for administrative and hospital-wide services. N.J.A.C. 8:43G-5.1 sets forth the requirements for structural organization. N.J.A.C. 8:43G-5.2 concerns the requirements for policies and procedures. N.J.A.C. 8:43G-5.3 identifies mandatory staff

qualifications. N.J.A.C. 8:43G-5.4 is reserved. N.J.A.C. 8:43G-5.5 sets forth requirements for patient services. N.J.A.C. 8:43G-5.6 enumerates those events that must be reported to the Department. N.J.A.C. 8:43G-5.7 sets forth requirements for staff education. N.J.A.C. 8:43G-5.8 is reserved. N.J.A.C. 8:43G-5.9 concerns department education programs. N.J.A.C. 8:43G-5.10 addresses funding for regionalized services. N.J.A.C. 8:43G-5.11 sets forth requirements for the occupational health structural organization. N.J.A.C. 8:43G-5.12 establishes requirements for occupational health policies and procedures. N.J.A.C. 8:43G-5.13 sets forth occupational health staff qualifications. N.J.A.C. 8:43G-5.14 sets forth the requirements for occupational health education. N.J.A.C. 8:43G-5.15 concerns occupational health continuous quality improvement methods. N.J.A.C. 8:43G-5.16 concerns planning for disasters. N.J.A.C. 8:43G-5.17 is reserved. N.J.A.C. 8:43G-5.18 concerns the hospital blood bank. N.J.A.C. 8:43G-5.19 involves clinical and pathological laboratories. N.J.A.C. 8:43G-5.20 addresses the electrocardiogram laboratory. N.J.A.C. 8:43G-5.21 sets forth requirements for outpatient and prevention services.

Subchapter six establishes standards for hospital anesthesia services. N.J.A.C. 8:43G-6.1 sets forth definitions pertinent to the subchapter. N.J.A.C. 8:43G-6.2 concerns requirements for policies and procedures. N.J.A.C. 8:43G-6.3 identifies staff qualifications of those

administering anesthesia. N.J.A.C. 8:43G-6.4 involves anesthesiologist availability. N.J.A.C. 8:43G-6.5 addresses anesthesia patient services. N.J.A.C. 8:43G-6.6 addresses required safety systems for anesthesia supplies and equipment. N.J.A.C. 8:43G-6.7 concerns maintenance and inspections of anesthesia supplies and equipment. N.J.A.C. 8:43G-6.8 addresses anesthesia patient monitoring. N.J.A.C. 8:43G-6.9 sets forth the requirements for anesthesia staff education and training. N.J.A.C. 8:43G-6.10 concerns anesthesia continuous quality improvement methods.

Subchapter seven establishes the requirements for hospital cardiac services, and addresses the following topical subject matters: N.J.A.C. 8:43G-7.1, scope and definitions; 7.2, cardiac surgery policies and procedures; 7.3, cardiac surgery staff qualifications; 7.4, reserved; 7.5, cardiac surgery staff time and availability; 7.6, reserved; 7.7, cardiac surgery patient services; 7.8 cardiac surgery space and environment; 7.9, cardiac surgery supplies and equipment; 7.10, staff education; 7.11, reserved; 7.12, cardiac surgery continuous quality improvement methods; 7.13, reserved; 7.14, cardiac catheterization polices and procedures; 7.15, cardiac catheterization staff qualifications; 7.16, cardiac catheterization staff time and availability; 7.17, cardiac catheterization patient services; 7.18, cardiac catheterization space and environment; 7.19, cardiac

catheterization supplies and equipment; 7.20, cardiac catheterization staff education and training; 7.21, cardiac catheterization quality assurance methods; 7.22, scope of pilot catheterization program; 7.23, requirements for licensure; 7.24, pilot catheterization program policies and procedures; 7.25, pilot catheterization program staff qualifications; 7.26, pilot catheterization program staff time and availability, 7.27, pilot catheterization program quality improvement; 7.28, percutaneous transluminal coronary angioplasty ("PTCA ") policies and procedures; 7.29, PTCA staff qualifications; 7.30 PTCA staff time and availability; 7.31, PTCA space and environment; 7.32, electrophysiology studies ("EPS") staff qualifications; 7.33, EPS staff time and availability; 7.34, board eligibility status; 7.35, pediatric cardiac services standards and scope; 7.36, pediatric cardiac surgery policies and procedures; 7.37, pediatric cardiac surgery staff qualifications; 7.38, pediatric cardiac surgery staff time and availability; 7.39, pediatric cardiac surgery space and environment; 7.40, pediatric cardiac surgery supplies and equipment; 7.41, pediatric cardiac surgery continuous quality improvement methods; 7.42, reserved; 7.43, pediatric cardiac catheterization policies and procedures; 7.44, pediatric cardiac catheterization staff qualifications; 7.45, pediatric cardiac catheterization continuous quality improvement methods; and 7.46, staff qualification waivers. It should be noted that the

cardiac services planning rule, N.J.A.C. 8:33E-1.1 et seq., contains specific provisions that supercede many of the provisions of Subchapter seven. It is the Department's intention to propose updates to Subchapter seven after readoption of this chapter, to bring it into alignment with the more up-to-date requirements of N.J.A.C. 8:33E-1.1 et seq.

Subchapter eight establishes the requirements for central supply services, and addresses the following topical subject matters: N.J.A.C. 8:43G-8.1, central supply policies and procedures; 8.2, central supply staff qualifications; 8.3, reserved; 8.4, central supply patient services; 8.5, reserved; 8.6, central supply space and environment; 8.7, central supply supplies and equipment; 8.8, reserved; 8.9, central supply staff education and training; 8.10, central supply quality improvement methods; 8.11, sterilizer patient services; 8.12, sterilizer space and environment; and 8.13, sterilizer supplies and environment.

Subchapter nine establishes the requirements for critical care and intermediate care services, and addresses the following topical subject matters: N.J.A.C. 8:43G-9.1, scope; 9.2, critical care structural organization; 9.3, reserved; 9.4, critical care policies and procedures; 9.5, critical care staff qualifications; 9.6, reserved; 9.7, critical care staff time and availability; 9.8, reserved; 9.9, critical care patient service; 9.10, reserved; 9.11, critical care space and environment; 9.12, reserved; 9.13,

critical care supplies and equipment; 9.14, critical care staff education; 9.15, reserved; 9.16, critical care continuous quality improvement methods; 9.17, reserved; 9.18, intermediate care standards; scope; 9.19, intermediate care structural organization; 9.20, intermediate care policies and procedures, 9.21, intermediate care staff qualifications; 9.22, reserved, 9.23, intermediate care staff education and training; and 9.24, intermediate care continuous quality improvement methods.

Subchapter ten establishes the requirements for hospital dietary services, and addresses the following topical subject matters: N.J.A.C. 8:43G-10.1, dietary policies and procedures, 10.2, reserved; 10.3, dietary staff qualifications; 10.4, dietary staff time and availability; 10.5, reserved; 10.6, dietary patient services; 10.7, reserved; 10.8, dietary staff education and training; 10.9, reserved; and 10.10, dietary continuous quality improvement methods.

Subchapter 11 establishes the requirements for hospital discharge planning, and addresses the following topical subject matters: N.J.A.C. 8:43G-11.1, discharge planning structural organization; 11.2, reserved; 11.3, discharge planning policies and procedures; 11.4 discharge planning staff qualifications, 11.5, discharge planning patient services; and 11.6, discharge planning continuous quality improvement methods.

Subchapter 12 establishes the requirements for emergency department and trauma services, and addresses the following topical subject matters: N.J.A.C. 8:43G-12.1, emergency department structural organization; 12.2, emergency department policies and procedures, 12.3, emergency department staff qualifications; 12.4, additional pediatric requirements; 12.5, emergency department staff time and availability; 12.6, definitions; 12.7, emergency department patient services; 12.8, reserved; 12.9, emergency department space and environment; 12.10, emergency department staff education and training; 12.11, emergency department continuous quality improvement methods; 12.12, trauma services scope and purpose; 12.13, trauma services definitions; 12 14; trauma services structural organization; 12.15, trauma services policies and procedures; 12.16, trauma services staff qualifications; 12.17, trauma services staff time and availability; 12.18, trauma services patient services; 12.19, trauma services environment; 12.20, trauma services quality improvement; 12.21, trauma services trauma registry; 12.22, trauma services compliance; and 12.23, pediatric trauma services.

Subchapter 13 establishes the requirements for hospital housekeeping and laundry services, and addresses the following topical subject matters: N.J.A.C. 8:43G-13.1, housekeeping polices and procedures; 13.2, housekeeping and staff qualifications; 13.3, reserved;

13.4, housekeeping patient services; 13.5, housekeeping supplies and equipment; 13.6, reserved; 13.7, housekeeping staff education and training; 13.8, housekeeping quality assurance methods; 13.9, laundry policies and procedures; 13.10, laundry staff qualifications; 13.11, laundry patient services; 13.12, laundry space and environment; 13.13, laundry supplies and equipment; 13.14, laundry staff education and training; and 13.15, laundry continuous quality improvement methods.

Subchapter 14 establishes the requirements for infection control and sanitation services, and addresses the following topical subject matters: N.J.A.C. 8:43G-14.1, infection control structural organization; 14.2, reserved, 14.3, infection control staff qualifications, 14.4, reserved; 14.5, infection control staff time and availability, 14.6, infection control patient services; 14.7, infection control staff education and training; 14.8, infection control quality assurance methods; 14.9, sanitation patient services; 14.10, sanitation space and environment; 14.11, sanitation quality assurance methods; 14.12, regulated medical waste policies and procedures; 14.13, solid waste policies and procedures; 14.14, solid waste patient services; 14.15, solid waste space and environment; and 14.16, solid waste supplies and equipment.

Subchapter 15 establishes the requirements for hospital medical records services, and addresses the following topical subject matters:

N.J.A.C. 8:43G-15.1, medical records structural organization; 15.2, medical records polices and procedures; 15.3, medical records patient services, 15.4, medical records staff qualifications; 15.5, staff education; 15.6, reserved; and 15.7, medical records quality assurance methods

Subchapter 16 establishes the requirements for hospital medical staff services, and addresses the following topical subject matters: N.J.A.C. 8:43G-16.1, medical staff structural organization; 16.2, medical staff policies and procedures; 16.3, medical staff qualifications, 16.4, reserved, 16.5, medical staff time and availability; 16.6, medical staff patient services, 16.7, medical staff education; and 16.8, medical staff quality assurance methods.

The Department is proposing that N.J.A.C. 8:43G-16.6 be amended to permit advanced practice nurses and physicians assistants to perform history and physical examinations in the hospital setting, whereas the existing rule permits only a physician to perform such tasks. This proposed amendment is consistent with the increased responsibilities afforded and high standards applied under the Advanced Practice Nurse Certification Act, N.J.S.A. 45:11-45, et seq., and the Physician Assistant Licensing Act, N.J.S.A. 9-27.10, et seq.

Subchapter 17 establishes the requirements for hospital nurse staffing, and addresses the following topical subject matters: N.J.A.C. 8:43G-17.1, nurse staffing; and 17.2, reserved.

Subchapter 18 establishes the requirements for nursing care services, and addresses the following topical subject matters: N.J.A.C. 8:43G-18.1, nursing care structural organization; 18.2, nursing care policies and procedures; 18.3, nursing care staff qualifications; 18.4, nursing care: use of restraints; 18.5, nursing care patient services, 18.6, nursing care service related to pharmaceutical services; 18.7, nursing care staff education and training; 18.8, reserved; and 18.9, nursing care quality assurance methods.

Subchapter 19 establishes the requirements for obstetric services, and addresses the following topical subject matters: N.J.A.C. 8:43G-19.1, scope of obstetrics standards; definitions; structural organization; 19.2, obstetrics policies and procedures; 19.3, obstetrics staff qualifications; 19.4, obstetrics staff time and availability; 19.5, obstetrics patient services; 19.6, maternal-fetal transport and neonatal transport; 19.7, obstetrics space and environment; 19.8, obstetric staff education and training; 19.9, reserved; 19.10, obstetric continuous quality improvement; 19.11, labor and delivery staff time and availability, 19.12, labor, delivery, anesthesia and recovery patient services; 19.13, post-partum policies and procedures

and staff time and availability; 19.14, post-partum patient services; 19.15, newborn care policies and procedures; 19.16, normal newborn nurse staff qualifications, staff time and availability; 19.17, intermediate nurse staff qualifications, staff time and availability; 19.18, neonatal intensive care nursery staff qualification, staff time and availability; 19.19, newborn care patient services; 19.20, newborn care supplies and equipment; 19.21, scope of nurse-midwifery standards; 19.22, nurse-midwifery structural organization; 19.23, nurse-midwifery policies and procedures, 19.24, nurse-midwifery staff qualifications; 19.25, nurse-midwifery staff education; 19.26, nurse-midwifery quality assurance methods; 19.27, obstetric/non-obstetric mix program; 19.28, obstetric/non-obstetric mix of patient services; 19.29, physical plant general compliance for new construction, alteration or renovation for newborn care; 19.30, functional area for newborn care; 19.31, general newborn care functional area requirements; 19.32, neonatal unit resuscitation area; 19.33, neonatal admission/observation/continuing care nursery or area; 19.34, normal newborn nursery or holding area; 19.35, infectious nursery; 19.36, intermediate care nursery, 19.37, intensive care nursery; 19.38, shared services; and 19.39 through 19.53, reserved.

The Department is proposing that N.J.A.C. 8:43G-19.15 be amended to reflect the requirement within P.L.2001, c.373, amending

N.J.S.A. 26:2-103.1, et seq., that every hospital which provides inpatient maternity services and every birthing center licensed in the State pursuant to N.J.S.A. 2H-1, et seq., shall be required to provide for newborn screening for hearing loss for all newborns born at the facility. Specifically, the department is proposing that whereas existing N.J.A.C. 8:43G-19.15(f) requires that hospitals have policies and procedures for screening newborns for "high risk factors associated with hearing impairment," the section as amended would require that hospitals have policies and procedures for "screening all newborns for hearing impairment, in accordance with N.J.S.A. 26:2-103.1, et seq." Moreover, the proposed amendments would require that hospitals and birth centers shall, (1) screen all newborns for hearing impairment using electrophysiologic measures, (2) screen all newborns for high risk indicators associated with hearing loss using criteria established at N.J.A.C. 8:19-1.6, prior to discharge or no later than one month of age, (3) complete and report to the department all specified components of the electronic birth certificate, including the hearing screening results within one week of discharge, and (4) designate personnel permitted to administer electrophysiological screening such as licensed physicians, licensed audiologists, and persons under their supervision. Finally, whereas existing N.J.A.C. 8:43G-19.15(f) requires that the facility shall

within one week of the infant's discharge send copies of the Newborn Hearing Screening Report Form for all at risk newborns to the department or enter the data electronically through the Department's electronic birth registration system, N.J.A.C. 8:43G-19.15(f), as amended, would require the hospital or birth center to establish policies and procedures, in accordance with N.J.A.C. 8:19-1.3 and 1.4, for the provision of follow-up services for newborns that do not pass or receive electrophysiological screening in one or both ears and for those that are identified as being at risk of developing a hearing loss.

Subchapter 20 establishes the requirements for hospital employee health services, and addresses the following topical subject matters: N.J.A.C. 8:43G-20.1, employee health policies and procedures; 20.2, employee health services; 20.3; reserved; 20.4, employee health education; 20.5, reserved; and 20.6, employee health continuous quality improvement methods.

Subchapter 21 establishes the requirements for oncology services, and addresses the following topical subject matters: N.J.A.C. 8:43G-21.1, scope of oncology standards; 21.2, oncology structural organization; 21.3, reserved; 21.4, oncology policies and procedures; 21.5, oncology staff qualifications; 21.6, reserved; 21.7, oncology staff time and availability; 21.8, reserved; 21.9, oncology patient services; 21.10, reserved; 21.11,

oncology space and environments; 21.12, reserved; 21.13, oncology supplies and equipment; 21.14, reserved; 21.15, oncology staff education; 21.16, reserved; and 21.17, oncology continuous quality improvement methods.

Subchapter 22 establishes the requirements for pediatric services, and addresses the following topical subject matters: N.J.A.C. 8:43G-22.1, scope of pediatrics and pediatric intensive care standards; 22.2, pediatrics and pediatric intensive care policies and procedures; 22.3, pediatric and pediatric intensive care patient services; 22.4, reserved; 22.5, pediatrics and pediatric intensive care supplies and equipment; 22.6, pediatrics and pediatric intensive care staff education; 22.7, reserved; 22.8, pediatrics and pediatric intensive care quality assurance methods; 22.9, scope of pediatrics standards; 22.10, pediatrics staff qualifications; 22.11, reserved; 22.1 pediatrics space and environment; 22.13, scope of pediatric intensive care standards; 22.14, pediatric intensive care structural organization; 22.15, pediatric intensive care staff qualifications; 22.16, pediatric intensive care staff time and availability; 22.17, pediatric intensive care patient services; 22.18, reserved; 22.19, pediatric intensive care space and environment; 22.20, pediatric intensive care supplies and equipment; 22.21 reserved; and 22.22, pediatric intensive care continuous quality improvement methods.

Subchapter 22A establishes the requirements for the licensure designation of children's hospital, and addresses the following topical subject matters: N.J.A.C. 8:43G-22A.1, scope of children's hospital designation standards; 22A.2 organizational structure; 22A.3, continuous quality improvement; 22A.4, medical staff and teaching program; 22A.5, building and facilities; and 22A.6, essential special care services.

Subchapter 23 establishes the requirements for hospital pharmacy services, and addresses the following topical subject matters: N.J.A.C. 8:43G-23.1, pharmacy structural organization, 23.2, pharmacy polices and procedures, 23.3, pharmacy staff qualifications; 23.4, pharmacy staff time and availability; 23.5, reserved, 23.6, pharmacy patient services; 23.7, reserved; 23.8, pharmacy space and environment; 23.9, pharmacy staff education and training; 23.10, pharmacy continuous quality improvement methods; and 23.11, reserved.

Subchapter 24 establishes the requirements for plant maintenance and fire and emergency preparedness, and addresses the following topical subject matters: N.J.A.C. 8:43G-24.1, plant maintenance structural organization, 24.2, plant maintenance policies and procedures; 24.3, plant maintenance staff qualifications; 24.4, plant maintenance services, 24.5, reserved; 24.6, plant maintenance staff education; 24.7, reserved; 24.8, physical plant general compliance for new construction, alteration or

renovation; 24.9, through 24.12, reserved; 24.13, fire and emergency preparedness; and 24.14, reserved.

Subchapter 25 establishes the requirements for post mortem procedures, and addresses the following topical subject matters: N.J.A.C. 8:43G-25.1, polices and procedures; 25.2, post mortem staff qualifications; 25.3, post mortem patient services; 25.4, post mortem space and environment and 25.5, post mortem supplies and equipment.

Subchapter 26 establishes the requirements for psychiatric services, and addresses the following topical subject matters: N.J.A.C. 8:43G-26.1, scope of psychiatry standards; 26.2, psychiatry policies and procedures; 26.3 psychiatry staff qualifications; 26.4, reserved; 26.5, psychiatry staff time and availability; 26.6, reserved; 26.7, psychiatry patient services; 26.8, reserved; 26.9, psychiatry space and environment; 26.10, reserved; 26.11, psychiatric supplies and equipment; 26.12, psychiatry staff education; 26.13, reserved; 26.14, psychiatry quality assurance methods.

The Department is proposing that N.J.A.C. 8:43G-26.7 be amended to permit advanced practice nurses and physicians assistants to perform history, physical examinations and psychiatric evaluations in the hospital setting, whereas the existing rule permits only physicians and psychiatrists to perform such tasks. This proposed amendment is consistent with the

increased responsibilities afforded and high standards applied under the Advanced Practice Nurse Certification Act, N.J.S.A. 45:11-45, et seq., and the Physician Assistant Licensing Act, N.J.S.A. 9-27.10, et seq.

Subchapter 27 establishes the requirements for continuous quality improvement programs, and addresses the following topical subject matters: N.J.A.C. 8:43G-27.1, continuous quality improvement structural organization; 27.2, continuous quality improvement policies and procedures; 27.3, continuous quality improvement staff qualifications; 27.4, reserved; 27.5, continuous quality improvement patient services; 27.6, performance measurement and assessment system.

Subchapter 28 establishes the requirements for radiology and radiation oncology services, and addresses the following topical subject matters: N.J.A.C. 8:43G-28.1, radiology structural organization; 28.2, radiology policies and procedures; 28.3, through 28.4, reserved; 28.5, radiology continuous quality improvement methods; 28.6, reserved; 28.7, diagnostic services staff qualifications, mandatory; 28.8, diagnostic services staff time and availability; 28.9, reserved; 28.10, diagnostic services patient services; 28.11, reserved; 28.12, diagnostic services supplies and equipment; 28.13, radiation oncology services staff qualifications; 28.14, radiation oncology services staff time and availability; 28.15, reserved; 28.16, radiation oncology patient services; 28.17,

reserved; 28.18, radiation oncology services supplies and equipment; 28.19, radiation therapy continuous quality improvement methods; 28.20, staff education; 28.21, reserved; 28.22, megavoltage radiation oncology (MRO) program utilization; 28.23, independent verification of MRO equipment calibration; 28.24, data to be maintained and reported.

Subchapter 29 establishes the requirements for physical and occupational therapy, and addresses the following topical subject matters: N.J.A.C. 8:43G-29.1, physical therapy policies, procedures; 29.2, reserved; 29.3, physical therapy staff qualifications; 29.4, reserved; 29.5, physical therapy staff time and availability; 29.6, physical therapy patient services; 29.7, reserved; 29.8, physical therapy space and environment; 29.9, physical therapy supplies and equipment; 29.10, physical therapy staff education; 29.11, reserved; 29.12, physical therapy quality assurance methods; 29.13, occupational therapy policies and procedures; 29.14, reserved; 29.15, occupational therapy staff qualifications; 29.16, reserved; 29.17, occupation therapy patient services; 29.18, reserved; 29.19, occupational therapy space and environment 29.20, occupational therapy supplies and equipment; 29.21, occupational staff education; 29.22, reserved; and 29.23, occupational therapy quality assurance methods.

The Department is proposing the repeal of Subchapter 30 governing renal dialysis services in its entirety. New rules proposed at

Subchapter 30 establish requirements for the provision of renal dialysis services in hospitals. The proposed repeal and new rules are the work of a technical committee, comprised of representatives from the Department and renal dialysis professionals from New Jersey's health care industry, which was convened to review and revise licensing standards for renal dialysis in both hospitals and ambulatory care facilities. The primary aim of this effort was to update the renal dialysis licensing standards, which have not been substantially revised since 1990, to reflect current renal dialysis practice patterns. The proposed new rules set forth in Subchapter 30 recognize the fact that renal dialysis services that were formerly provided within the hospital are now largely being provided on an outpatient basis, often in distinct off-site ambulatory care facilities that may or may not be licensed as an off-site ambulatory care facility on the hospital's license. Therefore, these proposed new rules in Subchapter 30 specifically address the provision of renal services by hospitals in both the acute inpatient and chronic outpatient settings. In doing so, the new rules indicate that many of the licensure requirements for this service, which were previously duplicated in Subchapter 30 (that is, N.J.A.C. 8:43G-30.2, 30,8, 30.9, 30.11, 30.13, 30.16, and 30.17) are to be found in the ambulatory care facility licensing requirements for renal dialysis services (N.J.A.C. 8:43A-24) and are cited by reference as "general provisions" in

the proposed new rules (N.J.A.C. 8:43G-30.3 and 30.4), which are simultaneously undergoing amendments, repeals and new rules in a companion proposal.

The proposed new rules in Subchapter 30 are summarized as follows:

Proposed N.J.A.C. 8:43G-30.1 sets forth the scope of the licensure requirements for renal dialysis services and includes, by reference, the standards that are required for licensed ambulatory care facilities providing hemodialysis and/or peritoneal dialysis services as set forth at N.J.A.C. 8:43A-24. The proposed new section indicates that many of the licensure requirements for these hospital services can be found in the ambulatory care facility licensing requirements for renal dialysis services (N.J.A.C. 8:43A-24), which are simultaneously proposed for amendments, repeal and adoption of new rules in a companion proposal. Since renal services in the hospital setting can be provided acutely to inpatients as well as on an ambulatory basis to chronic renal patients, the proposed new rules include specific references to those sections of N.J.A.C. 8:43A-24 that are to be included and excluded from each licensure category of renal dialysis service delivery.

Proposed N.J.A.C. 8:43G-30.2 sets forth the definitions of the terms “ambulatory dialysis” and “patient care technician” that are used within this subchapter.

Proposed N.J.A.C. 8:43G-30.3 sets forth the general licensure provisions for inpatient renal dialysis services, as set forth in the ambulatory care facility rules at N.J.A.C. 8:43A-24, that either are applicable or excluded from the licensure review process.

Proposed N.J.A.C. 8:43G-30.4 sets forth the general licensure provisions for an on-site, separate designated renal dialysis unit or service, as set forth in the ambulatory care facility rules at N.J.A.C. 8:43A-24, that either are applicable or excluded from the licensure review process.

Proposed N.J.A.C. 8:43G-30.5 sets forth the physical plant requirements for renal dialysis facilities. Specifically, the section sets forth requirements for privacy, hand washing facilities, gross floor space per dialysis unit, handicap accessibility, equipment storage, and toilet facilities. This section addresses the same topics as existing N.J.A.C. 8:43G-30.14 and 30.15, which are proposed for repeal as part of this proposal. Additional new language is added to indicate that renal dialysis units comprised of less than four stations would not require a nursing station since only a single nurse would be required to monitor the patients at those few stations.

Proposed N.J.A.C. 8:43G-30.6 sets forth the staffing requirements for inpatient dialysis services. This includes the presence of a

nephrologist during the initial dialysis treatment of a patient and for any patient with a life-threatening situation. Nursing staff to patient ratios of no greater than one licensed professional nurse to three patients are proposed, except in the critical care setting where the ratio would be one to one. These staffing qualifications and staff to patient ratios address the same topics as existing N.J.A.C. 8:43G-30.3 and 30.5, which are proposed for repeal as part of this proposal. New language is added to indicate that critically ill patients would require a nurse to patient ratio of one to one.

Proposed N.J.A.C. 8:43G-30.7 sets forth the requirements for a written inpatient care plan for each patient that is developed by a multidisciplinary team and includes goals and expected outcomes. The requirements for these care plans are consistent with existing N.J.A.C. 8:43G-30.6, which is proposed for repeal as part of this proposal. However, proposed N.J.A.C. 8:43G-30.7(b) would require that each care plan must be discussed with the patient and implemented within 24 hours of admission. This change is appropriate for licensing standards that now apply to inpatient dialysis treatment only.

Subchapter 31 establishes the requirements for respiratory services, and addresses the following topical subject matters: N.J.A.C. 8:43G-31.1, respiratory care structural organization; definitions; 31.2,

respiratory care policies and procedures; 31.3, respiratory care staff qualifications; 31.4 reserved; 31.5, respiratory care staff time and availability; 31.6, reserved; 31.7, respiratory care patient services; 31.8, reserved; 31.9, respiratory care space and environment; 31.10, reserved; 31.11, respiratory care supplies and equipment; 31.12, respiratory care staff education; 31.13, reserved; and 31.14, continuous quality improvement methods.

Subchapter 32 establishes the requirements for same-day stay, and addresses the following topical subject matters: N.J.A.C. 8:43G-32.1, scope; 32.2, same-day surgery services structural organization; 32.3, same-day surgery services policies and procedures; 32.4, same-day surgery services staff qualifications; 32.5, same-day surgery services patient services; 32.6, reserved; 32.7, same-day surgery services space and environment; 32.8, reserved; 32.9, same-day surgery services continuous quality improvement methods; 32.10, same-day medical services standards; scope; 32.11, same-day medical services structural organizations; 32.12, same-day medical services policies and procedures; 32.13, same-day medical services staff time and availability; 32.14, same-day medical services patient services; 32.15, reserved; 32.16, same-day medical services space and environment; 32.17, reserved; 32.18, same-day medical services education; 32.19, reserved; 32.20, same-day

medical services continuous quality improvement methods; 32.21, observation services, scope; 32.22, observation service policies and procedures; and 32,23, observation service space and environment.

An amendment is proposed at N.J.A.C. 8:43G-32.22 that would indicate that policies and procedures must be established before hospitals may use licensed inpatient beds for patient observation purposes. In addition, an amendment at N.J.A.C. 8:43G-32.23 would remove the prohibition against the mixed use of observation and inpatient beds, so long as hospitals provide appropriate oversight as specified in the amendment. These amendments would serve to provide some relief from the sometimes hectic environment of the emergency room while at the same time provide an improved setting for the observation of patients by using licensed beds where a hospital is accountable for appropriate staffing levels.

Subchapter 33 establishes the requirements for social work services, and addresses the following topical subject matters: N.J.A.C. 8:43G-33.1, social work structural organization; 33.2, social work policies and procedures; 33.3, social work staff qualifications; 33.4 through 33.5, reserved; 33.6, social work patient services; 33.7, reserved; 33.8, social work space and environment; 33.9, social work staff education and training; and 33.10, social work continuous quality improvement methods;

Subchapter 34 establishes the requirements for surgical services, and addresses the following topical subject matters: N.J.A.C. 8:43G-34.1, surgery structural organization; 34.2, reserved; 34.3, surgery policies and procedures; 34.4, surgery staff qualifications; 34.5, surgery staff time and availability; 34.6, surgery patient services; 34.7, surgery space and environment; 34.8, surgery supplies and equipment; 34.9, surgery staff education; 34.10, reserved; 34.11, surgery continuous quality improvement methods; and 34.12, reserved.

Subchapter 35 establishes the requirements for post-anesthesia care services, and addresses the following topical subject matters: N.J.A.C. 8:43G-35.1, post-anesthesia care policies and procedures; 35.2, post-anesthesia care staff qualifications; 35.3, post-anesthesia care staff time and availability; 35.4, post-anesthesia care patient services; 35.5, reserved; 35.6, post-anesthesia care supplies and equipment; 35.7, post-anesthesia care staff education and training; 35.8, reserved; and 35.9, post-anesthesia care continuous quality improvement methods.

Subchapter 36 addresses the requirements for satellite emergency departments, and addresses the following topical subject matters: N.J.A.C. 8:43G-36.1, scope; 36.2, definitions; 36.3, services in satellite emergency departments; 36.4, child abuse and neglect; 36.5, patient rights; 36.6, administrative and structural organization; 36.7, reportable

events; 36.8, administrative and staff qualifications; 36.9, staff time and availability; 36.10, administrative and staff education; 36.11, occupational health structural organization; 36.12, disaster planning; 36.13, mandatory equipment; 36.14, continuous quality improvement; and 36.15, physical plant.

Subchapter 37 establishes the requirements for extracorporeal shock wave lithotripsy services (ESWL). This subchapter contains a single subsection which references the licensure requirements for ESWL services that are set forth in the licensing rule for ambulatory care facilities at N.J.A.C. 8:43A-29.

Subchapter 38 establishes the requirements for long-term acute care hospitals, and addresses the following topical subject matters: N.J.A.C. 8:43G-38.1, scope; 38.2, compliance with rules and laws; 38.3, special hospital policies and procedures; 38.4, special hospital staff qualifications; 38.5, staff time and availability; and 36.6, continuous quality improvement.

As the Department has provided a 60-day comment period for this notice of proposal, this notice is excepted from the calendar requirements, pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

The Health Care Facilities Planning Act and amendments thereto, P. L.1971, c.136 & 138, codified at N.J.S.A. 26:2H-1 et seq., enjoin the Department of Health and Senior Services to protect and promote the public health and safety in New Jersey. The Act mandates the Department to develop "standards and procedures relating to the licensing of health care facilities and the institution of additional health care services" to ensure the continuity and accessibility of health care services. This purpose is served through the readoption with amendments of the hospital licensing rules, codified at N.J.A.C. 8:43G-1.1 et seq. and the repeal and new licensing rules governing renal dialysis services at N.J.A.C. 8:43G-30.1 et seq. This proposal establishes minimum licensure requirements for the provision of all health care services provided by licensed acute care hospitals.

Establishing rules that set minimum requirements in the operation of acute care hospitals is necessary to protect the public health and safety. Facilities must employ qualified patient care staff who possess a certain skill level in order to provide the services required by the patients under their care. Hospitals must ensure continuity and coordination of health care services and keep accurate records of patient care provided. Officers and administrators of licensed acute care hospitals must

appropriately direct and support acute care hospital services and provide oversight of the quality of care.

Given the potential benefits to patients accruing from acute care hospital services, it is important that hospitals providing these services maintain satisfactory levels of patient care. This is especially true in light of the challenges presented to acute care hospitals by rapid changes in the demand for services and evolving service modalities in an increasingly competitive health care environment. There exists a need to maintain acceptable measures of facility performance in order to continue to protect consumers of hospital-based services. The Department maintains that the proposed readoption with amendments, repeal and new rules would fulfill this need and ensure a high level quality of care, leading to improved health, safety and overall wellness of patients receiving acute care hospital services, including renal dialysis services.

Economic Impact

The Department foresees minimal or no financial consequences of either the proposed readoption with amendments or the repeal and new rules. Little additional cost to hospitals or the State is expected. Because both the proposed readoption with amendments and new rules maintain acute care hospital licensure standards without undue burden, the

Department does not expect the industry to incur significant expenses in order to comply with the rules.

The proposed readoption with amendments, repeal and new rules will allow flexibility in management and administrative practices, such as in developing policies and procedures best suited to their individual circumstances; in hiring and allocating staff to best meet patient care needs; and in deciding whether and in what manner to provide services. This will allow facilities to conserve resources by determining the most efficient deployment of services and personnel. Further, the use of various professional staff members in patient assessment, treatment planning, and delivery of care promotes continuity and coordination of care to reduce duplication, overlap, and fragmentation of services while ensuring that patients receive all necessary services.

Federal Standards Analysis

Federal regulations govern the operation of acute care hospitals, as set forth in C.F.R. T.42, Ch. IV, Refs & Annos. The Centers for Medicare & Medicaid Services of the Department of Health and Human Services, established in its Conditions of Participation for Hospitals, Subchapter G: Standards and Certification, codified at 42 C.F.R. Part 482, the standards hospitals must follow to participate in the Federal programs. These Conditions of Participation serve as a survey mechanism for selected

hospitals participating as providers in the Medicare and Medicaid Programs. In general, the Conditions of Participation are not comprehensive and have not been updated since 1991. Accordingly, there are rules contained within N.J.A.C. 8:43G that exceed Federal standards. The readoption with amendments, repeals, and new rules proposed in N.J.A.C. 8:43G, for example, contain two subchapters, Subchapter 5 and Subchapter 12, relating to ”Hospital Administration and General Hospital-Wide Policies” and “Emergency Department and Trauma Services,” respectively, that exceed Federal requirements. N.J.A.C. 8:43G-5.2(c) requires acute care hospitals to treat all patients regardless of their ability to pay. This requirement is based on the statutory provisions set forth at N.J.S.A. 26:2H-18.64 and is intended to ensure equal access to quality hospital services. Similarly, the proposal contains emergency room staffing and training requirements that exceed Federal standards only to the extent that the proposal quantifies and elaborates upon Federal standards that require “appropriate” staffing levels and training that do not provide suitable licensure criteria. The Department has found it essential to set minimum standards to assure quality. There is no way for the Department to ascertain whether the minimum standards proposed exceed what hospitals would provide in any event to meet clinical standards of practice, but if there is increased cost as a result, the

concomitant level of quality assurance achieved justifies the increased cost.

I, Acting Commissioner of the Department of Health and Senior Services, certify that the above statement permits the public to accurately and plainly understand the purposes and expected consequences of the proposed amendment.

_____
Fred M. Jacobs, M.D., J.D.
Acting Commissioner

Jobs Impact

The Department does not anticipate that the rules proposed for readoption with amendment or the proposed repeal and new rules would result in the generation or loss of jobs.

Agriculture Industry Impact

The proposed readoption with amendments, repeals and new rules would have no impact upon the agriculture industry in New Jersey.

Regulatory Flexibility Statement

The proposed readoption with amendments, repeals and new rules impose requirements only on acute care hospitals licensed in New Jersey, which are not considered “small businesses” within the meaning of the Regulatory Flexibility Act, N.J.S.A. 52:14b-15 et seq. Therefore the rules proposed for readoption with amendments, repeals and new rules impose

no requirements on small businesses, and no regulatory flexibility analysis is necessary. The proposed new rules would update licensure requirements for hospital-based renal dialysis providers to ensure quality health care service delivery. Continued compliance with these licensure standards is necessary in the interest of public health and safety for all facilities that provide acute care hospital services.

Smart Growth Impact

The proposed readoption with amendments, repeal and new rules would have no impact upon the achievement of smart growth and implementation of the State Development and Redevelopment Plan.

Full text of the proposed readoption may be found in the New Jersey Administrative Code at N.J.A.C. 8:43G.

Full text of the proposed repeal may be found in the New Jersey Administrative Code at N.J.A.C. 8:43G-30.

Full text of the proposed amendments and new rules follows (additions indicated in boldface thus; deletions indicated in brackets [thus]):

8:43G-1.4 Information and complaint procedure

(a) Questions regarding hospital licensure may be addressed to the [Inspections Program or the Licensing and Certification] Certificate of Need and Acute Care Licensure Program at the following address:

New Jersey State Department of Health and Senior Services

[Division of Health Facilities Evaluation and Licensing]

Division of Health Care Quality and Oversight

[CN- 367] P.O. Box 360

Trenton, NJ 08625-[0367] 0360

[(609) 588-7725] Current address and contact information can be obtained at the Department's website address:

www.state.nj.us/health/hcsa/hcsaforms.html

(b) To make a complaint about [a] any New Jersey licensed [hospital or nursing home] health care facility, call:

1-800-792-9770 (toll-free hotline)

8:43G-2.1 Certificate of Need

(a) Where, in accordance with N.J.S.A. 26:2H-1 et seq., as amended, a Certificate of Need is required, a hospital shall not be instituted, constructed, expanded or licensed to operate except upon application for and receipt of a Certificate of Need issued by the Commissioner of the Department of Health and Senior Services.

(b) Application forms for a Certificate of Need and instructions for completion may be obtained from:

Certificate of Need and Acute Care Licensure Program

[Division of Health Planning and Resources Development]

Division of Health Care Quality and Oversight

New Jersey State Department of Health and Senior Services

[CN] PO Box 360

Trenton, New Jersey 08625-0360

(c) (No change.)

8:43G-2.2 Application for licensure

(a) Where applicable, following receipt of a Certificate of Need as a hospital, any person, organization, or corporation desiring to operate a hospital shall make application to the Commissioner for a license on forms prescribed by the Department. Such forms may be obtained from the Department's website address www.state.nj.us/health/hcsa/hcsaforms.html or from:

Director

[Licensing, Certification and Standards

Division of Health Facilities Evaluation and Licensing

New Jersey State Department of Health

PO Box 367

Trenton, New Jersey 08625-0367]

Certificate of Need and Acute Care Licensure Program

Division of Health Care Quality and Oversight

New Jersey State Department of Health and Senior Services

P.O. Box 360

Trenton, New Jersey 08625-0360

(b) - (j) (No change.)

8:43G-2.3 Newly constructed or expanded facilities

(a) The application for a license pursuant to N.J.A.C. 8:43G-2.2 for the operation of a new hospital shall include written approval of final construction of the physical plant by:

[Health Facilities Construction Service

Division of Health Facilities Evaluation and Licensing

New Jersey State Department of Health

CN 367

Trenton, NJ 08625-0367]

Health Plan Review

Division of Codes and Standards

Department of Community Affairs

P.O. Box 815

Trenton, New Jersey 08625-0815

Telephone: 609-633-8151

(b) An on-site inspection of the construction of the physical plant shall be made at the Department's discretion by representatives of the [Health Facilities Construction Service] Acute Care Survey Program to verify that the building has been constructed in accordance with the final architectural plans approved by the Department.

(c) Any health care facility which intends to undertake any alteration, renovation, or new construction of the physical plant, whether a Certificate of Need is required or not, shall submit plans to the [Health Facilities Construction Service of the Department] Health Plan Review Program of the Department of Community Affairs for review and approval prior to the initiation of any work.

8:43G-2.4 Surveys and temporary license

(a) When the written application for licensure pursuant to N.J.A.C. 8:43G-2.2 is approved and the building is ready for occupancy, a survey of the facility by representatives of the Division of Health [Facilities Evaluation and Licensing] Care Quality and Oversight of the Department

shall be conducted at the Department's discretion to determine if the facility meets the standards set forth in this chapter.

1. Representatives of the Division of Health [Facilities Evaluation and Licensing] Care Quality and Oversight of the Department shall discuss the findings of the survey, including any deficiencies found, with representatives of the hospital facility.

2. The hospital facility shall notify the Division of Health [Facilities Evaluation and Licensing] Care Quality and Oversight of the Department in writing when the deficiencies, if any, have been corrected. Following review of the hospital facility's report, the Division of Health [Facilities Evaluation and Licensing] Care Quality and Oversight's Acute Care Survey Program may schedule one or more surveys of the facility prior to occupancy.

(b) (No change.)

(c) No hospital facility shall accept patients in any new service, unit, or facility until the hospital has a written approval and/or license issued by the [Licensing and Certification] Certificate of Need and Acute Care Licensure Program of the Department.

(d) - (e) (No change.)

8:43G-4.1 Patient rights

(a) Every New Jersey hospital patient shall have the following rights, none of which shall be abridged by the hospital or any of its staff. The hospital administrator shall be responsible for developing and implementing policies to protect patient rights and to respond to questions and grievances pertaining to patient rights. These rights shall include at least the following:

1. To receive the care and health services that the hospital is required to provide under N.J.S.A. 26:1-1 et seq. and rules adopted by the Department of Health and Senior Services to implement this law;

2. - 30. (No change.)

31. To expect and receive appropriate assessment, management and treatment of pain as an integral component of that person's care, in accordance with N.J.A.C. 8:43E-6.

8:43G-16.6 Medical staff patient services

(a) (No change.)

(b) Each patient admitted to the hospital shall have a medical history and physical examination that includes a provisional diagnosis performed by a physician, advanced practice nurse or physician assistant within seven days prior to admission or within 24 hours after admission. If the history and physical were performed within seven days prior to

admission, the patient's history and physical examination record completed by the attending physician, advanced practice nurse or physician assistant shall be included in the medical record, with any subsequent changes recorded at the time of admission.

(c) – (f) (No change.)

8:43G-19.15 Newborn care policies and procedures

(a) – (e) (No change.)

(f) Policies and procedures for screening all newborns for [high risk factors associated with] hearing impairment, in accordance with [N.J.S.A. 26:2-101 et seq.] N.J.S.A. 26:2-103.1 et seq. shall [be as follows] require that the hospital or birth center:

1. [A licensed physician or registered professional nurse shall screen the newborn using the Newborn Hearing Screening Report Form of the New Jersey Hearing Evaluation Council and the Special Child Health Services Program of the Department.

2. The facility shall send copies of the Newborn Hearing Screening Report Form for all at risk newborns, within one week of the infant's discharge to the Special Child Health Services Program of the Department or enter the data electronically through the New Jersey Department of Health and Senior Services Electronic Birth Certificate System, in

accordance with N.J.A.C. 8:2] Screen all newborns for hearing impairment using electrophysiologic measures;

2. Screen all newborns for high-risk indicators associated with hearing loss, using criteria established at N.J.A.C. 8:19-1.6 prior to discharge or no later than one month of age;

3. Complete and report to the department all specified components of the Electronic Birth Certificate, including the hearing screening results within one week of discharge, in accordance with N.J.A.C. 8:19-1.2;

4. Designate personnel permitted to administer electrophysiologic screening as licensed physicians, licensed audiologists, and persons under their supervision; and

5. Establish policies and procedures, in accordance with N.J.A.C. 8:19-1.3 and 1.4 for the provision of follow-up services for newborns that do not pass or receive electrophysiologic screening in one or both ears and for those that are identified as being at risk of developing a hearing loss.

(g) – (h) (No change.)

8:43G-26.7 Psychiatry patient services

(a) (No change.)

(b) All patients shall receive a complete history and physical examination by a physician, advanced practice nurse or physician assistant within 24 hours of admission to the psychiatric unit.

(c) - (d) (No change.)

(e) A written psychiatric evaluation shall be performed of each patient by a psychiatrist, advanced practice nurse or physician assistant within 24 hours of admission to the unit.

(f) - (p) (No change.)

SUBCHAPTER 30. RENAL DIALYSIS

8:43G-30.1 Scope of renal dialysis standards

These standards shall apply to both hemodialysis and peritoneal dialysis units. In addition to the rules of this subchapter, hospitals providing inpatient renal dialysis services or an on-site, separate designated unit or service for ambulatory patients shall also comply with N.J.A.C. 8:43A-24 in accordance with Sections 3 and 4 below.

8:43G-30.2 Definitions

The following terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise:

"Ambulatory dialysis" means the performance of a regular course of maintenance dialysis therapy on an outpatient basis.

"Inpatient dialysis" means dialysis therapy provided to either:

1. A hospitalized individual who abruptly sustains loss of kidney function, in whom dialysis is required as a temporary life-supporting measure and in whom recovery of kidney function is expected; or

2. A hospitalized individual with end stage renal disease who requires a regular course of maintenance dialysis therapy.

"Patient care technician" means unlicensed dialysis facility staff who has been specifically trained and demonstrates competency to provide direct patient care, under the direct supervision of a registered professional nurse, to individuals receiving dialysis services.

8:43G-30.3 General provisions; inpatient renal dialysis services

Hospitals providing inpatient renal dialysis services shall comply with both the rules of this subchapter and with the rules at N.J.A.C. 8:43A-24, with the exception of 24.7, 24.13 and 24.15.

8:43G-30.4 General provisions; ambulatory renal dialysis services

Hospitals providing an on-site, separate, designated unit or service for ambulatory renal dialysis patients shall comply with both the rules of this subchapter and with the rules at N.J.A.C. 8:43A-24.

8:43G-30.5 Physical plant requirements for inpatient renal dialysis units

(a) The treatment area for inpatient renal dialysis services shall be an open planned area separated from administrative and service areas.

(b) The minimum dimensional requirements for each dialysis station shall be:

1. There shall be a minimum width of 10 feet along the service wall.

2. The floor area within the cubicle curtain of each dialysis station shall be at least 80 square feet and shall not include the area of the service wall.

3. There shall be 30 inches of clear space around each machine and lounge, except that one side of the machine may be installed flush against the wall.

4. There shall be a minimum of four feet between beds and/or lounges.

5. The dimensional requirements listed in (b) 1 through (b)4 above shall apply to those facilities initially licensed six months or later from the effective date of these rules.

6. In the case of new construction or renovation involving at least 25 percent of the physical plant, hospital-based ambulatory renal dialysis units shall be required to conform to the standards provided in (b)1 through (b)4 above.

(c) Cubicle curtains around each patient station shall be provided for privacy and dignity.

(d) A nurses' station shall be located within the open treatment dialysis area for a unit of four or more dialysis stations and shall provide visibility of all patients' stations. This visibility condition shall apply to those facilities licensed six months from the effective date of this chapter. However, in the case of new construction or renovation involving at least 25 percent of the physical plant, hospital-based ambulatory renal dialysis units shall be required to conform to the standards of this section.

(e) Charting facilities for nurses and doctors shall be provided.

(f) Hand washing facilities shall be provided at a ratio of one hand sink per every four dialysis stations and shall be distributed throughout the dialysis area.

(g) The following requirements shall be met for the size and location of each treatment area utilizing two or more dialysis stations for inpatient renal dialysis services:

1. A support space, which shall be adjacent to the open treatment area;

2. Separate clean and soiled work or utility rooms shall be available within a reasonable distance. These facilities may be shared;

3. A separate janitor's closet, which may be shared, shall be provided for in the renal suite. The closet shall contain a floor receptor or service sink and storage space for housekeeping supplies and equipment;

4. If a separate employee kitchen or dining area is provided in the suite, it shall be separated from the patient area and shall not be utilized by patients;

5. A lounge, locker room and staff toilet with hand washing facilities, which shall be available for staff;

6. A medication station that includes a work counter with hand washing facilities, refrigerator, and locked storage for syringes, biologicals and drugs, and which may be either:

i. A room or area designated to store and prepare individual patients' medication for administration, located in a space that is under the nursing staff's visual control; or

ii. A room or area designated to prepare individual patients' medication for administration, in which patients' medication is self-contained in a medication-dispensing machine, such as a Pyxis system or other such system approved for use by the Department, and which may be located at the nurses' station, in a clean work room, or in another space that is under direct control of the nursing or pharmacy staff;

7. A storage room or rooms, which shall be located either within or outside of the suite, which shall house the supplies and equipment necessary to maintain the machines for the dialysis suite. At least one week of operational supplies must be available in the facility;

8. Storage space for medical waste shall be provided until it is properly disposed;

9. If patient toilet rooms are provided, they shall have doors equipped with hardware which will permit access by staff in any emergency; and

10. If home training is provided, patient education rooms or areas shall be equipped with a sink for hand washing.

(h) For hospitals using contract or outside vendors to manage inpatient dialysis services, the hospital shall assure that appropriate documentation from the vendor verifying the training competencies and health status of staff is available upon request of the Department.

8:43G-30.6 Staffing requirements for inpatient dialysis services

(a) A nephrologist shall be present prior to the initiation of the following:

1. A patient's first inpatient dialysis treatment; and

2. Any patient with a life-threatening situation, as determined by medical staff, which requires an emergency dialysis.

i. In the case of emergency dialysis, the nephrologist shall be present during the dialysis and until the patient is deemed stable.

(b) The staffing ratio in the inpatient dialysis setting shall be no greater than one registered nurse to three patients, except in the critical care setting which shall be a ratio of one to one. Staffing shall be increased if warranted by the acuity needs of the patients.

(c) In those instances where the staffing ratio requirement is one to one, a registered nurse with a minimum of six months experience in hemodialysis, obtained within the last 24 months, shall provide the service. In those instances where the staffing requirement is other than one to one, for the first three patients, a registered nurse meeting the requirement identified above shall provide the treatments.

(d) An inpatient facility providing dialysis services shall have at least one registered nurse providing treatments to the first three patients.

There shall be an additional registered nurse, licensed practical nurse, or trained technician to assist the required registered nurse for the next three patients. There shall be two additional staff, one of which is a registered nurse, for each additional group of one to six patients.

8:43G-30.7 Inpatient Care Plan

(a) A written plan of care for each patient shall be developed by a multidisciplinary team consisting of, at least, a nephrologist, a registered professional nurse, a dietitian, and a licensed social worker (the current outpatient dialysis care plan for previously diagnosed ESRD patients may be used to meet the requirement for the social worker review). The plan of care shall specify goals and expected outcomes.

(b) The written care plan for each inpatient dialysis patient shall be discussed with the patient and/or family, and implemented within 24 hours of admission to the facility.

8:43G-32.22 Observation service policies and procedures

(a) The hospital shall have a clearly defined plan and written policies and procedures for the use of an observation service that are reviewed at least once every three years, revised as needed, and implemented. These policies and procedures shall include at least:

1. – 4. (No change.)

5. Use of beds on an inpatient unit for observation as set forth at N.J.A.C. 8:43G-32.23(b) below.

8:43G-32.23 Observation service space and environment

(a) (No change.)

(b) The hospital [shall not] may mix observation beds and inpatient beds in the same room [.] provided the following requirements are met:

1. Observation patients are included in the patient-to-nurse staffing ratio of the nursing unit on which the observation patient is placed; and

2. Policies and procedures specific to the use of an inpatient unit for observation purposes are in place prior to the commencement of this practice.

(c) Observation beds shall not be considered licensed beds unless observation patients are placed in licensed beds pursuant to subsection (b) above.